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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,642	08/04/2003	William Suttle Peters	13634.4003	7193

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EXAMINER
ALTER, ALYSSA M

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/634,642	PETERS ET AL.	
	Examiner	Art Unit	
	Alyssa M. Alter	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 19-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 19-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 20, 2006 has been entered.

Response to Arguments

Applicant's arguments, filed on March 20, 2006, with respect to claims 1-17 and 19-29 have been fully considered and are persuasive. The Applicant states that Lederman discloses in the claims that the balloon is "separately positionable with respects to the stent". Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Dobak, III et al. (US 5,827,171) or Dobak, III et al. (US 5,820,542).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 17 and 19-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 17 and 19 recite the limitation "the fluid

conducting tube" in claim 17, line 2. There is insufficient antecedent basis for this limitation in the claim.

Also, claim 20 recites the limitation "the gas carrying tube" in claim 20, lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-11, 13-14, 16-17, 23-26 and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Dobak, III et al. (US 5,827,171). Dobak, III et al. discloses an intravascular circulatory assist device with an outer balloon, inner balloon and a stent.

As to claims 1-2, 7-8 and 25, figure 1 depicts catheter 12 with the inner balloon 14 is the balloon or chamber and the outer balloon is a protective balloon 18, which acts as a shell. The stent 20 is disposed within balloon 16 and is an expandable frame. Thus it is balloon or chamber expandable.

As to claims 3, 24 and 29, since the balloon 14 is located on the inside of the stent 20, the balloon is attached to the inner wall of the frame.

As to claim 4, figure 3 displays a self-expanding stent 20.

As to claims 5-6, "the stent 20 used in this embodiment (figure 2) is the thermally expanding stent 20 made of a material such as nitinol"(col. 7, lines 37-38). Nitinol is a nickel-titanium alloy, which is a shape memory alloy and is also a spring material.

As to claim 9, "the stent 20 is an expandable, substantially cylindrical, lattice of elongated elements of plastic or metal. It can be similar to cardiovascular stents known in the art"(col. 5, lines 38-39). The examiner considers the lattice of elongated elements to be a lattice of wires.

As to claim 10, "the balloons 14, 16, 18 are made of a flexible material which can expand up to a desired size, or diameter, after which the material essentially does not expand further, even if the pressure inside the balloon is increased further. Such materials, and the processes used in their fabrication, are widely used in the manufacture of balloons for angioplasty"(col. 5, lines 16-22). Since the balloons cover the stents, the examiner considers the balloons to be comprised of a fabric and thus the stents are covered with a fabric.

As to claim 11, the balloon forms a coating around the stent.

As to claims 13 and 14, since the balloon is located inside the lumen of the stent, the balloon extends around the full circumference of the frame lumen. Furthermore, since the balloon extends around the full circumference, it inherently extends around a part of the circumference.

As to claims 16-17, 23 and 30, "when the outer balloon 16 is in the expanded state, a control space 26 is created between the outer balloon 16 and the inner balloon 14. This control space 26 is repetitively evacuated and pressurized with a control fluid,

to achieve the expansion and collapse of the inner balloon 14"(col. 6, lines 31-35). As seen in figure 1 there is a control fluid pressure source P is connected to the balloon chamber(s) via the conducting tube (depicted as "A"). This control fluid affects the control space 26 to facilitate a pumping action and as such the balloon or chamber (balloon 14) is connected to the control fluid pressure source.

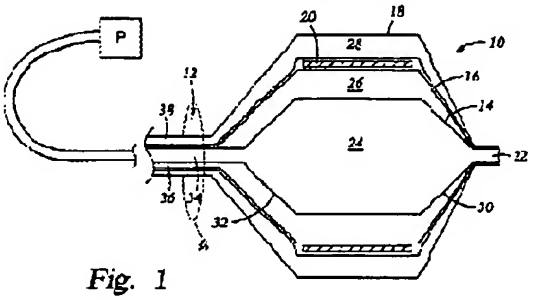

Fig. 1

As to claim 26, circulatory assist device "could be used to provide blood flow into the feeding artery of a selected organ, such as a coronary artery"(col. 3, lines 1-3).

As to claim 28, the circulatory assist device has a port 22 for the flow of blood or other vascular fluid. Therefore, blood would flow through the balloon and stent instead of glowing over the surface of the shell or protective balloon 18. Furthermore, it has been held that the recitation that an element is "adapted to" perform a function in not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison, 69 USPQ 138.*

2. Claims 1-17, 23-26 and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Dobak, III et al. (US 5,820,542). Dobak, III et al. discloses a modified circulatory assist device with a protective membrane, a housing, pumping membrane or balloon and a stent.

As to claims 1-2, 7-8 and 25, figure 1 depicts catheter 12 with a pumping membrane 14 as the balloon or chamber and the protective membrane 18, which acts

as a shell. The stent 20 is disposed within housing 16 and is an expandable frame. In the alternative, the shell could be the housing 16 surrounding the stent.

As to claims 3, 24 and 29, since the pumping membrane 14 or balloon is located on the inside of the stent 20, the balloon is attached to the inner wall of the frame.

As to claim 4, "FiG. 1, could also be used with the self-expanding stent 20"(col. 9, lines 48-49).

As to claims 5-6, "the stent 20 used in this embodiment is the thermally expanding stent 20 made of a material such as nitinol"(col. 9, lines 18-19). Nitinol is a nickel-titanium alloy, which is a shape memory alloy and is also a spring material.

As to claim 9, "the stent 20 is an expandable, substantially cylindrical, lattice of elongated elements of plastic or metal. It can be similar to cardiovascular stents known in the art"(col. 7, lines 19-21). The examiner considers the lattice of elongated elements to be a lattice of wires.

As to claim 10, "the housing 16 and the membranes 14,18 can be made of a flexible material which can expand up to a desired size, or diameter, after which the material essentially does not expand further, even if the pressure inside the housing or membranes is increased further. Such materials, and the processes used in their fabrication, are widely used in the manufacture of balloons for angioplasty"(col. 6-7, lines 64-67 and 1-3). Since the housing could consist of two laminated membranes with the stent disposed within them and the examiner considers the membranes to be comprised of a fabric, the stent as a result would be covered with a fabric.

As to claim 11, the housing forms a coating around the stent.

As to claims 13 and 14, since the pumping member 14 is located inside the lumen of the stent, the pumping member 14 extends around the full circumference of the frame lumen. Furthermore, since the pumping member 14 extends around the full circumference, it inherently extends around a part of the circumference.

As to claim 12-15, in the alternative interpretation that the shell is housing 16, the partially extending around the circumference is exhibited in figure 18 where the pumping member is smaller than the stent and thus does not extend completely through the lumen. Furthermore, the areas of the stent that do no have the pumping member disposed within the lumen are considered to be bare. A copy of figure 18 depicts the bare portion of the stent, as indicated by the highlighted sections in the figure at right.

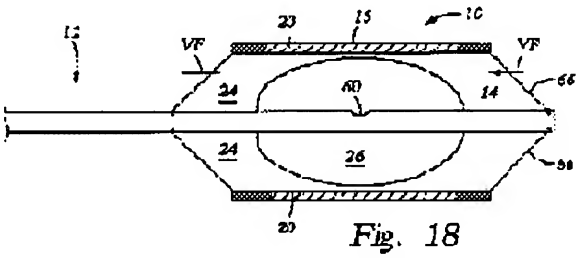

Fig. 18

As to claims 16-17, 23 and 30, "when the housing 16 is in the expanded state, a control chamber 26 is created between the housing 16 and the pumping membrane 14. This control chamber 26 is repetitively evacuated and pressurized with a control fluid, to achieve the expansion and collapse of the pumping membrane 14"(col. 8, lines 12-17). As seen in figure 1 there is a control fluid pressure source P is connected to the balloon chamber(s) via the conducting tube (depicted as "A"). This control fluid affects the control chmber 26 to facilitate a pumping action and as such the pumping membrane 14 is connected to the control fluid pressure source.

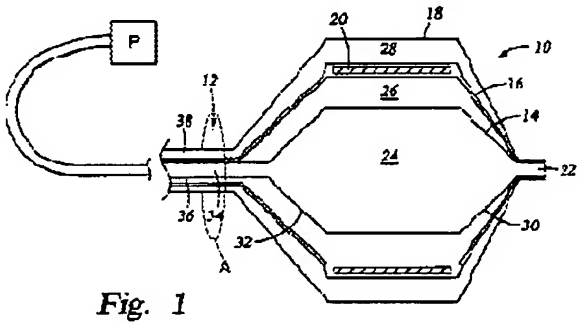

Fig. 1

As to claim 26, circulatory assist device "could be used to provide blood flow into the feeding artery of a selected organ, such as a coronary artery"(col. 3, lines 61-36).

As to claim 28, the circulatory assist device has a port 22 for the flow of blood or other vascular fluid. Therefore, blood would flow through the balloon and stent instead of glowing over the surface of the shell or protective balloon 18. Furthermore, it has been held that the recitation that an element is "adapted to" perform a function in not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison, 69 USPQ 138.*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 21-22 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dobak, III et al. (US 5,827,171) or Dobak, III et al. (US 5,820,542). Dobak, III et al. discloses the claimed invention except for the sternotomy. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the placement of the assist device as taught by Dobak, III et al. with implantation by a sternotomy since it was known in the art that to implant medical devices into the patients chest cavity via a sternotomy. Furthermore, it is also well know in the art to modify a surgical procedure to meet specific patient needs.

As to claim 22, Dobak, III et al. discloses the claimed invention except for the aortotomy. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the placement of the assist device as taught by Dobak, III et al. with connecting the device via a aortotomy since it was known in the art to implant s known to insert a balloon into the thoracic aorta to augment blood flow, as taught by Dobak, III et al. '542. Furthermore, it is also well know in the art to modify a surgical procedure to meet specific patient needs.

2. Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dobak, III et al. (US 5,827,171) or Dobak, III et al. (US 5,820,542) in view of Lederman (US 6,210,318). Dobak, III et al. discloses the claimed invention except for the gas carrying tube. Lederman teaches that it is known to utilize fluid or gas to inflate and deflate a pumping balloon as set forth in column 7, lines 32-33. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the fluid as taught by Dobak, III et al. with a gas as taught by Lederman, since both fluids facilitate the inflation and deflation of the pumping balloon.

Claim Objections

1. Claim 22 is objected to because of the following informalities: "claim 26,, further ". Appropriate correction is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alyssa M. Alter

Alyssa M Alter
Examiner
Art Unit 3762

AA

JEFFREY R. JASTRZAB
PRIMARY EXAMINER
4/7/06